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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,652	05/01/2006	Alex Rapoport		3203

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ALEX RAPOPORT
ARIOZOROV 41A
RISHON LE ZION, 75214
ISRAEL

EXAMINER

LIPITZ, JEFFREY BRIAN

ART UNIT	PAPER NUMBER
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3769

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,652	RAPOPORT, ALEX	
	Examiner	Art Unit	
	JEFFREY B. LIPITZ	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9-11,15-21 and 23-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9-11,15-21 and 23-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Drafts, Person's Patent Drawing, Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/20/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments/amendments filed November 1, 2010 with respect to the 112 rejections of claims 1, 5, 10, 15, 19 and 24 have been fully considered and are persuasive. These 112 rejections have been withdrawn.

Applicant's arguments/amendments with respect the 112 rejections of claims 5, 6, 8 and 10 have been fully considered but they are not persuasive. Applicant has not provided any structure in these claims, but instead relies on a functional limitation. However, it is unclear how the apparatus is configured to perform this functional limitation. Examiner recommends claiming the combination and configuration of elements that provides these functional limitations. These rejections have been maintained.

Applicant asserts that none of the references teach that the target volume is on the symmetry axis beneath the skin surface. This is not true. Koziol discloses a full lenticular ablation (Figure 7), which necessary positions the target volume on the symmetry axis.

The prior art rejections have been modified in accordance with Applicant's amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5, 6, 8, 10 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, Applicant recites “radiation impinging on the surface on the symmetry axis is less than the maximum fluence of the radiation on the skin surface”. Does the radiation impinge the surface at the symmetry axis? It appears that when the radiation impinges the axis, it is well beneath the skin’s surface. Please clarify the meaning of this limitation.

Regarding claims 1 and 9, Applicant recites “the reflective beam collector has convergence only in one plane”. This recitation is unclear, because Applicant does NOT provide any structure to support the functional limitation.

Regarding claims 5, 6, 8, and 10, these recitations are intended uses of the invention. It is unclear how any of them necessarily modify the structure of the invention; and thus it is unclear how they modify the scope of the invention. See the Response to arguments supra for more details.

Regarding claims 6, 10 and 20, Applicant now recites that the redirected radiation is “essentially non-focused” at the target volume. It is unclear how this limitation is intended to limit the scope of the invention. First, the phrase “essentially non-focused” literally has no definite meaning. A beam is either focused or it is not focused. Second, if a beam is being directed, it can reasonably be assumed to be focused with respect to its new direction. The term “focus” in optics is used to connote a beam converging to a single focal point or focus. In this instance, the term appears to

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be inappropriate. These claims have only been rejected under 112 2nd paragraph, because it is unclear to the Examiner how to interpret this recitation.

Regarding claim 15, Applicant recites that radiation has convergence controllable independently in two planes; however, it is unclear what elements enable this control.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 15-21 and 25 are rejected under 35 U.S.C. 101 because the disclosed invention is directed to non-statutory subject matter. The claims do not affirmatively state in the body of the claims that they are performed by a particular machine or elements and the steps do not result in a transformation of underlying subject matter from one state to another. See *In re Bilski*, 88 USPQ 2d 1385 (2008). The only element mentioned is a source, however, it is unclear what structure performs the remaining steps, or how those steps transform underlying subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-7, 9-11, 15-21 and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Azar et al. (7066929), hereinafter Azar in combination with Koziol (5425727).

Regarding claims 1, 3, 9, 15, 17 and 23, Azar teaches performing selective photothermolysis on subcutaneous tissues using a plurality of beams that have energy insufficient to cause damage at the surface, but overlap within the tissue to cause damage (Abstract). Thus, radiation at the surface is less than the maximum fluence of the radiation within the tissue. Azar does NOT teach using Applicant's claimed structure.

Attention is now directed to Koziol who teaches a light source (30; Figure 2) that emits light that is divided up when it reflects off of reflectors (12a-h), which are rotatable about hub (18; Column 5, Lines 45-57). This divided up light is then reflected off of peripheral reflectors (14a-h), which directs the light to a depth within the eye (Column 5, Lines 62- 66). The light beams are clearly illustrated as converging towards a volume (e.g. the stroma) that could be overlap the symmetry axis of the device in the case of a full lenticular ablation (Figure5). Koziol illustrates that the symmetry and rotation axes are collinear. Kozil's radiation necessarily has a maximum energy fluence greater than the fluence along the symmetry axis, since the divided beams impinge the surface at a displaced distance and at an angle relative to the axis (Figure 2). Koziol's radiation necessarily has a lower radiation at the tissue surface than the predetermined energy fluence, since the radiation with the predetermined fluence is divided before it reaches the surface, and only converges once inside the tissue. Koziol's peripheral reflectors (14a-h) are rigidly attached to their hubs; and therefore, necessarily provide

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convergence in at most one plane. Koziol teaches providing a desired depth via focusing of the radiant energy (Col. 2, Lines 47-49), which is necessarily independent from the control of the light in the plane of the tissue surface.

It would have been obvious to use the beam converter of Koziol with the method and device of Azar, because it would have enabled the input beam to be divided into more sub-beams, which would have reduced the fluence at the surface. It also would have been advantageous to use the device of Koziol to perform the method of Azar, because it would have required one light source, which would have reduced the number of elements relative to Azar's current apparatus. Furthermore, it would have been advantageous to use a device where the symmetry axis and the rotational axis are collinear, because it would have enabled the beams to recombine over a greater volume within the tissue, which would have again reduced the total energy at the surface and provided a larger treatment region. It also would have been obvious to use the converter of Koziol with the device/method of Azar, because the main point of Azar's invention is to provide a method that causes damage deep within the skin without causing epidermal damage (Abstract).

Regarding claims 4, 11, 18 and 25, Azar teaches using radiation between 550-800 nm (Col 6), which is well within Applicant's claimed range.

Regarding claims 5, 19, 24 and 26-28, Koziol inherently teaches that the input radiation is greater than the redirected radiation, since the input radiation is divided. None of the elements have optical power.

Regarding claims 7 and 21, Azar teaches that the light incident on the skin is collimated by a collimating optic (82; Figure 6). Although Koziol does NOT provide such

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an optic for the redirected light, it would have been obvious to provide one because doing so would reduce the interference of light beams/pulses with other beams/pulse redirected from the same reflector. This reduction in interference would result in more predictable and reproducible results.

Regarding claim 16, Koziol teaches that the central reflectors (12a-h) are rotated during irradiation such that the incident radiation is radially spread out (Column 7, Lines 60-69). It would have been obvious to also rotate during the method of Azar, because Azar also uses a scanner for providing forming a pattern in tissue. It would particularly advantageous to rotate while performing the method because it would inherently enable a larger volume of tissue to be irradiated in a smaller amount of time.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY B. LIPITZ whose telephone number is (571)270-5612. The examiner can normally be reached on Monday to Thursday, 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry M. Johnson III can be reached on (571)272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JEFFREY B LIPITZ/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art
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